

REMARKS

This Amendment is filed in response to the Office Action mailed December 11, 2008 (the "*Office Action*") and the Examiner Interview conducted May 5, 2009 (the "*Examiner Interview*"). In this Amendment, claims 33 and 62 are amended, and claims 34, 51-53, 63, and 64 are unchanged. Claims 1-32, 35-50, and 54-61 were previously cancelled. Following entry of this amendment, claims 33, 34, 51-53, and 62-64 shall be pending.

In the *Office Action*, claims 33, 34, 51-53, and 62-64 are rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. SUMMARY OF EXAMINER INTERVIEW

On May 5, 2009, the Applicants' Counsel David J. McKinley and Shane S. Swanson conducted a telephonic interview with Examiner Nguyen. During the interview, Applicants' Counsel and Examiner Nguyen discussed (1) the functionality and configuration of the device of the referenced prior art, U.S. Patent No. 5,540,707 to Ressemann et al. ("*Ressemann et al.*"); (2) the Examiner's assertions that certain features recited in claim 33 were recited in functional-type language; and (3) the failure of *Ressemann et al.* to teach certain claim features.

With respect to the general discussion of the functionality and configuration of the embolus removal apparatus of *Ressemann et al.*, Applicants' Counsel pointed out that the relevant figures of *Ressemann et al.*, FIGS. 12-17, are shown in an orientation opposite to that of the figures showing the present invention as claimed in independent claim 33. Namely, that the removal element 16 of *Ressemann et al.* is oriented such that the distal end of the device is oriented on the left side of the figures and that the presently claimed device shown in FIGS. 17A-19B is oriented such that the distal end of the device is oriented on the right side of the figures. The parties also discussed that the proximal ends 202 of the wires 102 of *Ressemann et al.* are fixed to the outer shaft 188. *Ressemann et al.* at col. 22, lines 48-57. Furthermore, the parties discussed how

the device of *Ressemann et al.* is actually expanded by a distal displacement of the catheter shaft 188 relative to the inner coil 94. *Id.* at col. 23, line 62 through col. 24, line 7. Finally, the parties discussed that the wires 102 of *Ressemann et al.* are predisposed to return to a low profile, contracted configuration. *Id.* at col. 13, lines 53-65. The Examiner conceded that he had been comparing the Ressemann figures to the figures of the present application with the mindset that the devices in the figures were oriented similarly, rather than oppositely. The Examiner thanked the Applicants' Counsel for the clarification.

With respect to the discussion regarding the Examiner's assertions that certain features recited in claim 33 are recited in functional-type language, the Examiner suggested that the Applicants amend claim 33 such that these specific claim features are prefaced by the recitation "configured to." The Examiner indicated that such amendments would serve to overcome the Examiner's concerns for the asserted use of functional-type language.

With respect to the discussion regarding the failure of *Ressemann et al.* to teach certain claim features of the present invention, the Applicants' Counsel specifically argued that *Ressemann et al.* fail at least to teach or make obvious the claimed features of (1) a plurality of resilient members having proximal ends configured to freely slide over said inner tube, as recited in amended claim 33; and (2) wherein the outer tube is axially retractable to remove the constraint on the embolus removal apparatus such that the embolus removal apparatus is configured to automatically expand from said collapsed configuration to a deployed configuration upon said axial retraction of said outer tube, as recited in amended claim 33. In response to these arguments and in light of the discussion and clarification regarding the functionality and configuration of the apparatus of *Ressemann et al.*, the Examiner indicated that he would reconsider the pending rejections.

II. AMENDMENTS TO THE SPECIFICATION

Paragraph [0188] has been amended to correct an error that was only discovered during the preparation of the present Amendment. More particularly, the paragraph was amended to correctly recite reference number 732 instead of reference number 730. As evident from paragraph [0182], reference number 730 references to distal wire pairs, and reference number 732 and 736 reference free ends of the wire pairs 730. Entry of this amendment is respectfully requested.

III. AMENDMENTS TO THE CLAIMS

Claim 33 is amended to recite the term “configured to” as suggest by the examiner and discussed above in the Summary of the Examiner Interview section. This amendment addresses the Examiner’s concerns relating to the Examiner’s assertion that claim 33 uses functional-type language.

Claim 62 have been amended to more accurately recite the subject matter which the Applicants’ believe represents the present invention. Support for the amendment can be found throughout the present application as published in Publication No. 2004/0133232 and, more specifically, in paragraph [0182]. No new matter is entered through this amendment.

IV. REJECTIONS UNDER 35 U.S.C. § 112

Claims 33-34, 51-53, and 62-64 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More particularly, the Examiner asserts that the recitation of independent claim 33, a plurality of resilient members having proximal ends freely slidable over said inner tube, contains subject matter which is not described in the specification in such a manner so as to enable one of skill in the art to make and/or use the invention. In stating these rejections, the Examiner drew specific attention to the term “freely,” as recited in claim 33. The Applicants strongly disagree.

With reference to FIGS. 17B, 18B, 18C, 19A, and 19B, at paragraph **[0182]** of the present application, the Applicants disclose:

The clot removal wires 724 extend helically in the proximal direction and each wraps around the distal segment 690 of the reinforced inner tube 680. In a preferred embodiment, a distal wire pair 730 terminates at distal free ends 732, while a proximal wire pair 734 terminates at proximal free ends 736. The free ends 732 and 736 are separated by a sliding marker band 738. **The free ends 732 and 736 and sliding marker band 738 are free to slide over the distal segment 690.**

(Emphasis Added). As evident from the above passage. The claim features referenced by the Examiner are described in the specification in such a manner so as to enable one of ordinary skill in the art to make and/or use the claimed invention. Accordingly, withdrawal of these rejections and an indication of allowance is respectfully requested.

V. REJECTIONS UNDER 35 U.S.C. § 102

Claims 33, 34, 51, 53, and 62-64 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Ressemann et al.* Of these claims, claim 33 is an independent claim, and claims 34, 51, 53, and 62-64 are dependent claims that depend from claim 33. For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

As discussed during the *Examiner Interview*, at column 22, lines 48-57 and in FIGS. 13 and 14, *Ressemann et al.* teach that the proximal ends 202 of the wires 102 that form the removal element 16 are attached to the annular bearing member 204. The bearing member 204 is, in turn, coupled to the complementary bearing member 206, and the bearing member 206 is attached to the distal end 208 of the catheter shaft 188. *Id.* Additionally, at column 23, line 62 through column 24, line 7, *Ressemann et al.* teach:

Because the distal end 98 of the drive shaft 92 is fixed to the distal annulus 108 and the removal element 16, **distal axial movement of the**

catheter shaft 188 with respect to the drive shaft 92 reduces the axial distance between the distal annulus 108 and the bearing members 204 and 206. The bearing member 206 transmits force from the catheter shaft 188 to the bearing member 204, and, from there, to the wires 102. Opposite ends of the braided wires 102 are attached to the distal annulus 108 and the bearing member 204, respectively, such that reduction of the axial distance between the distal annulus 108 and the bearing member 204 causes the wires 102 to bow radially outwardly from the inner coil 94 of the drive shaft 92.

(Emphasis Added).

Ressemann et al. cannot be properly relied upon as anticipating the claimed invention for at least two reasons. First, *Ressemann et al.* fail to teach an embolus removal apparatus comprising a plurality of resilient members having proximal ends configured to freely slide over said inner tube, as recited in amended claim 33. To the contrary, *Ressemann et al.* teach that the proximal ends 202 of braided wires 102 are attached to bearing member 204. At FIGS. 13 and 14 and column 22, lines 48-57. Bearing member 204 is, in turn, coupled to the complementary bearing member 206, which is attached to the distal end 208 of the catheter shaft 188, i.e. the proximal ends 202 of the wires 102 are attached to the catheter shaft 188. *Id.*

While the proximal ends 202 of the removal element 16 may be slidable over the inner coil 94 of *Ressemann et al.*, due to the fact that the proximal ends 202 are attached to the catheter shaft 188, one of ordinary skill in the art would recognize that the proximal ends 202 are not configured to freely slide over inner coil 94. Any sliding of the proximal ends 202 of the removal element 16 relative to inner coil 94 would inherently not be of the removal element's 16 own accord but rather dictated by displacement of the catheter shaft 188.

Second, *Ressemann et al.* cannot be properly relied upon as anticipating the claimed invention because *Ressemann et al.* fail to teach an embolus removal

apparatus wherein the outer tube is configured to be axially retractable to remove the constraint on the embolus removal apparatus and whereby the embolus removal apparatus is configured to automatically expand from said collapsed configuration to a deployed configuration upon said axial retraction of said outer tube, as recited in amended claim 33. As discussed above and during the Examiner Interview, the removal element 16 of *Ressemann et al.* is inoperable to expand upon an axial retraction of catheter shaft 188 relative to the inner coil 94. At col. 23, line 62 through col. 24, line 7. An axial retraction of catheter 188 would cause the distance between the distal and proximal ends of removal element 16 to lengthen, thereby resulting in a **contraction** of removal element 16 to a low profile configuration—not an expanded configuration. *Id.*

Furthermore, any automatic change in configuration of the embolus removal apparatus of *Ressemann et al.* would be *from a deployed configuration to a collapsed or low profile configuration*—not from a collapsed configuration to a deployed configuration, as claimed in claim 33. At column 13, lines 53-65, *Ressemann et al.* teach that the wires 102 are comprised of a super-elastic alloy predisposed to return to the “original low profile, contracted condition.” One of ordinary skill in the art would therefore recognize that the removal apparatus of *Ressemann et al.* is **not configured to** automatically expand from said collapsed configuration to a deployed configuration upon said axial retraction of said outer tube without requiring axial movement or rotation of the guidewire, as claimed by the Applicants.

Nor are these failures of *Ressemann et al.* to teach or make obvious the present invention trivial. At paragraphs [0008] and [0011]-[0013], the Applicants describe that interventional procedures involving prior art embolus removal apparatuses, such as the embolus removal apparatus of *Ressemann et al.*, are highly, operator-skill-dependent and can be difficult, if not impossible, to perform in small, tortuous vessels. In contrast, the invention as claimed in claim 33 provides the advantages of employing a simpler, more compact design in which the removal apparatus automatically expands to a known configuration.

Considering the above, it is evident that *Ressemann et al.* fail to anticipate the Applicants' claimed invention. Hence, for at least the above reasons, it is submitted that claim 33 is novel over the cited prior art.

Turning to claims 34, 51, 53, and 62-64, these claims depend from claim 33 and thus for at least the same reasons as provided above, these claims are also novel over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

IV. REJECTIONS UNDER 35 U.S.C. § 103

Claim 52 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ressemann et al.* in view of U.S. Patent No. 5,167,239 to Cohen et al. ("*Cohen et al.*"). For at least the reasons set forth below, it is submitted that this prior art rejection should be withdrawn and the pending claim allowed.

In the *Office Action*, the Examiner asserts that *Ressemann et al.* disclose or make obvious the invention as claimed with the exception of the plurality of infusion ports located near said embolus removal apparatus recited in claim 52. The Examiner is referred to the previously presented arguments in this Amendment with regard to claim 33, from which this claim depends. For at least the same reasons provided above, *Ressemann et al.* fail to teach or make obvious the invention of claim 52.

Furthermore, *Cohen et al.* fail to make up for the deficiencies of *Ressemann et al.* *Cohen et al.* are directed towards an anchorable guidewire comprising an elongated guidewire body, an inner tube, and at least one inflatable anchoring balloon. At column 5, lines 13-26. *Cohen et al.* fail to disclose or make obvious an embolus removal apparatus, constraint of such an apparatus by an outer tube, or the configuration and automatic expansion of such an apparatus. Accordingly, at least for these reasons, it is submitted that this prior art rejection should be withdrawn and the pending claim 52 allowed. However, this claim further limits the claimed invention and thus is separately patentable over the cited prior art.

Applicant: Robert F. Rosenbluth et al.
Serial No.: 10/730,860
Art Unit: 3734

PATENT
Atty Docket: 388700-001BC

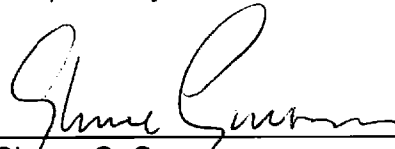
CONCLUSION

In view of the foregoing, it is submitted that pending claims 33, 34, 51-53, and 62-64 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any additional fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



Shane S. Swanson
Registration No. 52,263

Dated: May 7, 2009

INSKEEP INTELLECTUAL PROPERTY GROUP, INC.
Inskeep Intellectual Property Group, Inc.
2281 W. 190th Street, Suite 200
Torrance, CA 90504
Phone: 310-755-7800
Fax: 310-327-3466

Customer No. 37,374